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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,405	04/14/2004	Elaine Jacobson	NIAD 216.2 DIV	9384

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EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,405	JACCOBSON ET AL.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-21* is/are pending in the application.

4a) Of the above claim(s) *14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,15 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election **without traverse** of improved skin epithelialion in the reply filed on 1/8/2008 is acknowledged. Claims 14, 16 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim.

Claims 13, 15 and 18-21 are examined as far as they read upon the elected species.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 13, 15 and 18-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,750,234. Although the conflicting claims are not identical, they are not patentably distinct from each other because

both are directed to a method of increasing leptin levels and alleviating a condition alleviatable by increasing leptin levels by administering nicotinic acid or a nicotinic acid ester. The '234 patent defines improved skin epitheliation as a condition alleviatable by increasing leptin levels by administering nicotinic acid or a nicotinic acid ester (see col. 5, line 29).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2) Claims 13, 15 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Scivoletto (WO 98/52927).

The claims are directed to a method of increasing leptin levels using an effective amount of nicotinic acid or its ester wherein the said amount should be sufficient to increase leptin levels and to alleviate a condition alleviatable by increased leptin levels.

The limitation "skin epitheliation" is interpreted to mean a process where the skin epithelial layer would develop, such as would occur in normal skin homeostasis and remodeling, or healing. See Figure 1 of the current application.

Scivoletto teaches a pharmaceutical composition comprising a therapeutically effective amount of nicotinic acid or its derivatives (e.g., nicotinic esters, nicotinamide) to treat skin conditions(e.g., burns, acne, etc.) when the composition is applied topically, see abstract. With respect to the limitation wherein the alkyl chain of said nicotinic acid alkyl ester contains from 1-

22 carbon atoms, Scivoletto exemplifies methyl nicotinate (nicotinic acid ester with 1 carbon atom containing unsubstituted alkyl chain) in the patented composition, see pages 3-4. The skin condition (e.g., burns, acne) taught in Scivoletto is a skin wound (the interruption of continuity of any body tissues) and thus, Scivoletto teaches the recited limitation requiring skin epitheliation.

Although Scivoletto is silent about the recited limitation (i.e. increasing leptin level), modulation of leptin level is an underlying biological mechanism wherein the increased leptin levels are naturally occurring and achieved when the nicotinic acid or its ester is applied to treat skin wounds (e.g. burns or acne). Thus, this said biological mechanism (i.e., increasing leptin levels) via administering an effective amount of nicotinic acid or its esters for treating skin wounds, is considered to be inherent feature and the claims are anticipated. In the absence of a showing that these mechanisms of action are not present in the treatment of Scivoletto, one skilled in the art would have considered such properties (the increase of leptin) to be inherent in the application of the nicotinic acid ester.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.,* 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

3) Claims 13, 15, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Warshaw et. al (US 5,240,945).

Warshaw et al. teach nicotinic acid esters containing 7-12 carbon atoms (nicotinic acid has 6 carbon atoms) used in acne treatment. For example, topical hexyl nicotinate which contains 12 carbon atoms, improves rapidly and effectively lesions associated with acne conditions, see abstract and column 1, lines 22-45.

Again, the limitation "skin epitheliation" is interpreted to mean a process where the skin epithelial layer would develop, such as would occur in normal skin homeostasis and remodeling, or healing. See Figure 1 of the current application. Thus the teaching of Warshaw et al. for treating acne also reads on skin epitheliation.

It is noted again that the recited limitation (i.e. increasing leptin level) recited in claim 13 is an inherent feature which is naturally occurring and the increased leptin levels are achieved when a composition comprising a therapeutically effective amount of nicotinic acid ester containing 12 carbons is applied to treat the skin wounds (e.g., acne). *In re Best (supra)* is applied as above.

4) Claims 13, 15, 19 and20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernstein (US 4,505,896).

Bernstein teaches the use (i.e., treating acne) of nicotinic acid or nicotinamide (which contains 6 carbon atoms) via oral or topical administration used in the acne treatment, see abstract and examples at columns 2-3. As mentioned earlier, the recited limitation (i.e., increasing leptin level) as recited in claim 13 is an inherent feature which is naturally occurring

and the increased leptin levels are achieved when a composition comprising a therapeutically effective amount of nicotinic acid is administered orally or topically to treat the said skin wound (e.g., acne).

It is noted again that the recited limitation (i.e. increasing leptin level) recited in claim 13 is an inherent feature which is naturally occurring and the increased leptin levels are achieved when a composition comprising a therapeutically effective amount of nicotinic acid ester containing 12 carbons is applied to treat the skin wounds (e.g., acne). *In re Best (supra)* is applied as above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5) Claims 13, 15, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scivoletto (WO 98/52927).

As mentioned in the 102 rejection above (*supra*), Scivoletto teaches that nicotinic acid or nicotinic acid derivatives such as nicotinic acid esters is used effectively in the treatment of skin wound (e.g., burns or acne), thus including skin epithiliation.

Although Scivoletto teaches nicotinic acid or nicotinic acid esters, Scivoletto fails to mention a combination of nicotinic acid and at least one nicotinic ester, or a mixture of more than one nicotinic acid esters required by the instant claim 21.

However, the minor variations including the selection of optimal mixture among the effective species in order to determine the most effective treatment is well within the purview of the skilled artisan, and is obvious. One would have been motivated to make such modification (i.e., to substitute nicotinic acid, nicotinamide or nicotinic acid ester with a mixture of nicotinic acid and nicotinic acid esters, or a mixture of more than one nicotinic acid esters) because the mixture of different compounds would have counteracted the undesired side effect while maintaining the therapeutic efficacy. Modification of the pure nicotinic acid molecules is well known in the art, resulting in various derivatives thereof (e.g. nicotinamide, nicotinic esters such as methyl nicotinate) in order to reduce the side effects. Because each compound has different chemical properties (e.g., polarity, solubility, different degree of efficacy due to different reactivity against receptors), the efficacy would be beneficially modified when they mix these compounds. Thus one would have motivate to use the mixture of these compounds to maximize the therapeutic effectiveness with reasonable expectation of success because each compound has been known to be effective species for treating skin wounds, and thus skin epilthiliation.

One would have been motivated to combine these references and make the modification because they are drawn to the same technical field (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which with which the application is concerned. See MPEP § 2141.01(a).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is 571-272-9032. The examiner can normally be reached on Monday-Friday 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy A Lewis/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614